



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Rec'd 3/20/98 jlb

MAR 13 1998

Mr. Steven R. Sumsion
General Counsel
Nature's Way Products, Inc.
10 Mountain Springs Parkway
Springville, Utah 84663

Dear Mr. Sumsion:

This is in response to your letters of March 24, 1995, June 21, 1995, July 19, 1995, September 8, 1995, September 11, 1995, July 29, 1996, April 7, 1997 and September 22, 1997 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nature's Way Products, Inc. is making the following claims, among others, for the products:

Garlicin® CF

"Garlicin CF promotes the body's overall health, especially in the cold and flu season."

Echinacea

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

EchinaGuard

"EchinaGuard promotes well-being during cold & flu season."

Echinacea Root Complex

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

Echinacea with Ester-C

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

975-0163

LET 148

Echinacea with Golden Seal Root

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

Echinacea with Astragalus + Reishi

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

Echinacea with Golden Seal Root extract

"Helps promote well-being during the cold and flu season."

Echinacea Complex alcohol extract extract

"Helps promote well-being during the cold and flu season."

Cold Season Formula

"Cold Season Formula provides nourishment and nutritional support for the body's natural defense systems."

Echinacea

"Helps general well-being during the cold & flu season. *Echinacea (Echinacea purpurea)* helps promote general well-being during the cold and flu season.."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products and, in the case of "Cold Season Formula," the inclusion of the term "cold season" in the product name, suggest that they are intended to prevent, treat or mitigate a disease, namely the common cold and influenza. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they

Page 3 - Mr. Steven R. Sumsion

are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (File)
HFS-450 (file, r/f)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456;jel:3/13/98:docname:naturesw.adv:disc26

The Natural Choice

March 24, 1995

Elizabeth Yetley, Ph.D., R.D.
Acting Director, Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Yetley:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Garlicin® CF. The statement of nutritional support reads as follows:

"Garlicin CF promotes the body's overall health, especially in the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.



Steven R. Sumsion
General Counsel

lre

Sieve\Letter\Yet-Gar.CF2



The Natural Choice™

June 21, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea. The statement of nutritional support reads as follows:

"*Echinacea purpurea* helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion
General Counsel

lre

Steve\Letter\Kahl.Ech



The Natural Choice

July 19, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is EchinaGuard. The statement of nutritional support reads as follows:

"EchinaGuard promotes well-being during cold & flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion
General Counsel

lre

Steve\Letter\Kahl, EG

60: 1W 91 904 96

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS
HFS-450

16 Mountain Springs Parkway • Springville, Utah 84663 • Phone: 801/489-1500 • Fax: 801/489-1700



The Natural Choice™

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea Root Complex. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion
General Counsel

95 SEP 14 10:16

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450
Ire





The Natural Choice™

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea with Ester-C. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion

General Counsel

SEP 13 1995

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

lre

Save/Letter/Kahl, EC



The Natural Choice™

September 8, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea with Golden Seal Root. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion
General Counsel

95 SEP 14 A9:15

lre

Seve/Letter/Kahl/Egr

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

10 Mountain Springs Parkway • Springville, Utah 84663 • Phone: 801/489-1500 • Fax: 801/489-1700



The Natural Choice™

September 11, 1995

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea with Astragalus + Reishi. The statement of nutritional support reads as follows:

"Echinacea purpurea helps promote general well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Steven R. Sumsion
General Counsel

SEP 18 09:36 '95

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450
Seal/Letter/Label





The Natural Choice™

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

July 29, 1996

'96 AUG -6 P2:02

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea with Golden Seal Root extract. The statement of nutritional support reads as follows:

"Helps promote well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory Counsel

lre

Gordon/Letter/Kahl, EFA

48042



The Natural Choice™

July 29, 1996

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea Complex alcohol extract extract. The statement of nutritional support reads as follows:

"Helps promote well-being during the cold and flu season."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

A handwritten signature in cursive script, appearing to read "Gordon M. Walker".

Gordon M. Walker
Regulatory Counsel

lre

Gordon\Letter\Kahl.ECF

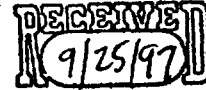
48042



The Natural Choice™

September 22, 1997

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204



Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Echinacea. The dietary ingredient that is the subject of the statement is Echinacea. The statement of nutritional support reads as follows:

"Helps general well-being during the cold & flu season. Echinacea (*Echinacea purpurea*) helps promote general well-being during the cold and flu season.."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type. Please note that this is a change from the first notification sent on June 21, 1995.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory/I.P. Counsel

Re

Gordon\Letter\Kahl.Ech

54892



The Natural Choice™

April 7, 1997

4/15/97

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has within the past 30 days, commenced marketing a dietary supplement which bears a statement of nutritional support.

The dietary supplement for which the statement is made is Cold Season Formula. The dietary ingredients that are the subject of the statement are Vitamins A and C. The statement of nutritional support reads as follows:

"Cold Season Formula provides nourishment and nutritional support for the body's natural defense systems."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

This statement of nutritional support is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker
Regulatory Counsel

lre
Gordon\Letter\Kahl.CS